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January 14, 2000

Office of Special Nutritionals (HFS-450)  
Center For Food Safety and Applied Nutrition  
**FOOD & DRUG ADMINISTRATION**  
200 C Street, S.W.  
Washington, D.C. 20204

Ref.: **Optimum Performance™ – Dietary Supplement for Men**

Dear Sir and/or Madam:

Pursuant to 21 CFR 101.93, please be advised that Herbalife International of America, Inc. has begun commercializing Optimum Performance™ – Dietary Supplement for Men, in the United States.

Optimum Performance™ – Dietary Supplement for Men is labeled and promoted with statements provided for in section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act.

1. **LABEL**

(Note: The label contains the ruled DSHEA disclaimer box which appears directly beneath the following copy.)

Optimum Performance™

Dietary Supplement for Men

Optimum Performance™ features natural testosterone precursors that can help men improve workout performance. It also may help burn fat and enhance intimacy.

2. **HERBALIFE FACT SHEET**

(Note: The asterisks appearing in the copy shown below relate to the ruled DSHEA disclaimer box which is asterisked and appears on the product literature.)

Optimum Performance™

Dietary Supplement for Men

*A superior, well-rounded dietary supplement that can help improve workout performance, may help burn fat and may help enhance intimacy.\**

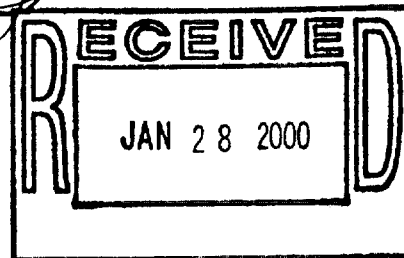
Herbalife has taken a balanced approach with Optimum Performance, a superior, well-rounded product featuring natural testosterone precursors that may help men improve their workout performance.\* In the process, Optimum Performance may help to burn fat and enhance stamina during intimate moments.\*

**Discussion Points**

- **A safe and natural way to improve intimate performance:** The herbs in Optimum Performance have a long and proven tradition of safe use, which have been shown to mildly enhance the libido.\* The best way to put it is this: Optimum Performance really works.

**Fast Facts**

- Contains a generous amount of *Androstenediol-5*, a natural testosterone precursor that is converted to the male hormone two to four hours after ingestion.\*
- Helps maintain a masculine edge with *Chrysin*, a plant isoflavone that inhibits the conversion of testosterone into estrogen.\*



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- Helps increase the biosynthesis of testosterone production due to the presence of *Pregnenolone*, a hormone precursor.\*
- May enhance intimate performance\* – includes *Muira puama*, a South American herb used by indigenous Rain Forest tribes for impotency, and *Epimedium*, an ancient Chinese herb taken for similar purposes.
- Further enhances intimacy via the Nitric Oxide precursor molecule *L-Arginine*.\*

3. **HERBALIFE TODAY NEWSLETTER**

(Note: The asterisks appearing in the copy shown below relate to the ruled DSHEA disclaimer box which is asterisked and appears on this page of the newsletter.)

Herbalife has taken a balanced approach with Optimum Performance, which features three natural testosterone precursors that may help men improve their workout performance.\* In the process, this product may help burn fat and may help enhance feelings of sensuality.\*

- Contains Androstenediol-5, a natural testosterone precursor that is converted to the male hormone two to four hours after ingestion.\*
- Increases biosynthesis of testosterone production, due to the presence of Pregnenolone and DHEA, a hormone precursor.\*
- Contains *Tribulus terrestris*, an Ayurvedic herb commonly known as “puncture vine,” which increases the pituitary gland’s output of lutenizing hormone, which may stimulate testosterone production.\*
- Helps maintain that masculine edge with Chrysin, a plant isoflavone that inhibits the conversion of testosterone into estrogen.\*
- Excellent for enhancing feelings of sensuality – includes Muira-Puama, a South American herb used by indigenous Rain Forest tribes for impotency, and Epimedium, an ancient Chinese herb taken for similar purposes.\*
- Contains Maca, a Peruvian herb used to help augment male sexual performance.\*
- May help enhance function due to the Nitric Oxide precursor molecule L-Arginine.\*

4. **PRODUCT FOCUS**

(Note: The asterisks appearing in the copy shown below relate to the ruled DSHEA disclaimer box which is asterisked and appears on the product literature.)

... Herbalife has taken a balanced approach with Optimum Performance, a dietary supplement featuring natural testosterone precursors that may help men improve their workout performance and burn fat – in addition to enhancing intimacy.\*

- Contains Androstenediol-5, a natural testosterone precursor that is converted to the male hormone two to four hours after ingestion.\*
- Includes *Tribulus terrestris*, an Ayurvedic herb commonly as “puncture vine,” which boosts testosterone production by increasing the pituitary gland’s output of lutenizing hormone.\*
- Also contains Chrysin, a plant isoflavone that inhibits the conversion of testosterone into estrogen.\* The biosynthesis of testosterone production is further increased thanks to the presence of Pregnenolone, another hormone precursor.\*
- May help enhance intimate performance because it contains Muira-Puama, a South American herb used by indigenous Rain Forest tribes for impotency, and Epimedium, an ancient Chinese herb taken for similar purposes.\*

5. **MINI PRODUCT BROCHURE**

(Note: The asterisks appearing in the copy shown below relate to the ruled DSHEA disclaimer box which is asterisked and appears on the product literature.)

With its special selection of herbs and natural hormone precursors, *Optimum Performance* may help men improve workout performance, help burn fat and enhance intimacy.\* Contains traditional herbs widely believed to stimulate the libido.\*

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Product labeling and literature prominently bears the required boxed statement, “These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.”

Herbalife International of America, Inc. certifies that the information contained in this notice is complete and accurate, and that the Company has substantiation that the foregoing statements are truthful and not misleading.

**Please do not hesitate to advise should you have any questions.**

Sincerely,

John P. Vennard

**File: Optimum Performance™ - Dietary Supplement for Men**

